

Date of Approval Letter: FEB 3 1999

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

NADA 141-097

IVOMEC[®] (ivermectin) Premix for Swine

+

BMD[®] (bacitracin methylene disalicylate)

Combination in Swine Feed

Sponsored by:

Merial Limited

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I. GENERAL INFORMATION

NADA Number: 141-097

Sponsor: Merial Limited
2100 Ronson Road
Iselin, New Jersey 08830-3077

Established Names: ivermectin
bacitracin methylene disalicylate

Trade Names: IVOMEC® Premix for Swine
BMD®

Marketing Status: over-the-counter (OTC)

II. INDICATIONS FOR USE

IVOMEC® Premix for Swine:

For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrogylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), threadworms (*Strongyloides ransomi*, adults and somatic larvae and prevention of transmission of infective larvae to piglets, via the colostrum or milk, when fed during gestation), lice (*Haematopinus suis*), and mange mites (*Sarcoptes scabiei* var. *suis*).

BMD® premixes:

- . For increased rate of weight gain and improved feed efficiency in growing and finishing swine.
- For control of clostridial enteritis caused by *Clostridium perfringens* in suckling piglets.
- . For control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery but where signs of disease have not yet occurred; or following an approved treatment of the disease condition

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND DOSAGE

The route of administration is oral, *via* Type B or Type C medicated feeds containing ivermectin and bacitracin methylene disalicylate.

IVOMEC® Premix for Swine Type A medicated article contains 0.6% ivermectin and is added to starter, grower, and finisher feeds at 300 g/ton to supply 1.8 g ivermectin per ton (2 ppm) of Type C medicated feed. This feed provides approximately 0.1 mg of ivermectin per kg body weight per day.

IVOMEC® Premix for Swine is added to complete feed at 1.5 kg per ton to supply 9.1 g ivermectin per ton (10 ppm) of feed. This Type C medicated feed is fed at the rate of 1 lb per 100 lb of body weight daily to adult and breeding swine to provide the recommended dose of 0.1 mg ivermectin per kg body weight.

BMD® Type A medicated article is sold in concentrations of 30,50,60 and 75 grams of bacitracin activity per pound for preparing Type C medicated feeds at the following recommended dosages.

10 to 30 g/ton	For increased rate of weight gain and improved feed efficiency in growing and finishing swine.
250 g/ton	For control of clostridial enteritis caused by <i>C. perfringens</i> in suckling piglets.
250 g/ton	For control of swine dysentery associated with <i>T. hyodysenteriae</i> on premises with a history of swine dysentery but where signs of disease have not yet occurred; or following an approved treatment of the disease condition.

The resultant feed containing both drugs is then fed as the only feed for durations as specified in 21 CFR 558.300 for ivermectin and 21 CFR 558.76 for bacitracin methylene disalicylate, but not for more than seven consecutive days, which is the recommended duration for ivermectin.

IV. EFFECTIVENESS

Data demonstrating the effectiveness of IVOMEC® Premix for Swine and BMD® for swine are contained in the respective single ingredient NADAs (ivermectin: NADA 140-974; bacitracin methylene disalicylate: NADA 46-592) and summarized in the respective FOI summaries.

Based on the data in the approved single ingredient applications, the burden to establish effectiveness of the combination uses effected by this original application has been met.

V. ANIMAL SAFETY

The target animal safety data for each individual drug are contained in the respective single ingredient NADAs (ivermectin: NADA 140-974; **bacitracin methylene disalicylate**: NADA 46-592) and summarized in the respective FOI summaries.

Additional safety studies were not required for this combination because: (1) the ingredient drugs have been approved as single ingredients, and (2) adequate information has been provided to show that these compounds are compatible when used in combination in swine feed.

VI. HUMAN SAFETY

A. Toxicity Tests

Toxicology studies supporting the established acceptable daily intake (ADI) for ivermectin and **bacitracin methylene disalicylate** are contained in the respective single ingredient NADAs (**ivermectin**: NADA 140-974; **bacitracin methylene disalicylate**: NADA 46-592) and summarized in the respective FOI summaries.

B. Safe Concentration of Residues

For swine the marker residue tolerance **and/or** safe concentration of residues areas specified in 21 CFR 556.344 for ivermectin and in 21 CFR 556.70 for **bacitracin methylene disalicylate**, respectively.

C. Residue Depletion Non-Interference Study: Trial ASR 14161

The purpose of this study was to determine the depletion of the marker residues of ivermectin in liver and **bacitracin methylene disalicylate** in muscle of swine administered **bacitracin methylene disalicylate** at its highest use level of 250 g/ton in combination with ivermectin at its use level of approximately 100 mcg/kg/day in complete feed. The study was required to determine if **either** drug, when administered in combination, interferes with the depletion of residues of the other from edible tissues and if either drug interferes with the analytical assay of the other.

1. Name and address of investigator: Merck & Co., Inc.

6498 Jade Road
Fulton, MO 65251

2. Test animals: Thirty-two crossbred pigs, sixteen females and sixteen castrated males, about nine weeks old and weighing 17.7 to 28.6 kg, were used. Pigs were ranked from heaviest to lightest within sex on Day 8, at which time one pig of each sex was selected at random to serve as the nonmedicated control (Group 1). The remaining thirty animals (Group 2) were assigned to six replicates of five

animals each, based on sex and body weight. In each replicate one pig was randomly allocated to each of the five slaughter days.

3. Route of Drug Administration and Time and Duration of Dosing: Group 1 received basal ration throughout the study. Group 2 was given basal ration that contained **bacitracin methylene disalicylate** at 250 g/ton from Day 0 to the termination of the study and that contained ivermectin at 1.8 #ton from Days 14 to 21.
4. Sample Collection: The two animals of Group 1 were sacrificed on Day 21. From Group 2 six animals, one from each replicate, were sacrificed at each of the following times: Day 21 (within six hours after removal of medicated feed), Day 22, Day 23, Day 24, and Day 26 (i.e. 0, 1,2,3, and 5 days after withdrawal of combination medicated feed). The liver was collected from each animal for assay of ivermectin marker residue and a sample of **longissimus** muscle was collected for assay of **bacitracin methylene disalicylate** marker residue.
5. Assay:
 - a. *ivermectin*: Marker residue assays were performed on swine liver samples using high pressure liquid chromatography-fluorescence. Prior to assaying the liver samples for ivermectin, a method validation and residue noninterference study was performed. The method was **successfully** validated at ivermectin fortification levels of 5.0 and 200 ppb. The noninterference study included fortification at 20 ppb ivermectin, 20 ppb ivermectin + 500 ppb **bacitracin**, and 500 ppb **bacitracin**. The study demonstrated that (a) **bacitracin** does not produce a fluorescent derivative either with or without the presence of ivermectin, and (b) it does not change the retention time or sensitivity of the ivermectin fluorescent peak. Recovery of ivermectin from the fortified samples was similar with and without bacitracin (mean recovery of 74°/0 in both cases), indicating that the presence of **bacitracin** does not interfere with the ivermectin assay.
 - b. *bacitracin methylene disalicylate*: Marker residue assays were performed on swine muscle samples using a microbiological assay with *Micrococcus luteus* as the assay organism. Prior to assaying the muscle samples for bacitracin **methylene disalicylate**, the method was validated in control muscle samples fortified with 0.02 units of **bacitracin/g**, the tolerance for bacitracin. Recovery of **bacitracin** ranged from 0.0165 to 0.0175 units/g with an average of 0.0171 units/g, 85.5°/0 of the theoretical level, An assay noninterference study was conducted with control muscle fortified with 0.02 units of **bacitracin/g**, 200 ppb ivermectin, and 0.02 units **bacitracin/g** + 200 ppb ivermectin. Recovery of bacitracin from the fortified samples was similar with and without ivermectin (mean recovery of 85.0°/0 with bacitracin alone and 84.2°/0 with bacitracin and ivermectin), indicating that the presence of ivermectin does not interfere with the bacitracin assay.

6. Results: Liver samples from the nonmedicated control animals did not contain detectable marker residues. The results for medicated animals are summarized in Table 6.1.

Table 6.1. Concentration (ng/mL) of 22, 23-dihydroavermectin B_{1a} (marker residue) in liver (target tissue) samples of medicated swine

Days after last drug	Mean (rig/g)	Range (rig/g)
0	47	34 to 70
1	23	15 to 28
2	14	6to 19
3	8.7	4to 14
5	2.5	1 t o 4

7. Noninterference Conclusions:

The withdrawal period was determined as the earliest time at which the one-sided 95% confidence limit on the 99th percentile of log liver marker residue is below the tolerance. Statistical analysis, using linear regression methods, yielded a withdrawal period of 4 days for the tolerance of 20 ppb. This period is one day less than that determined in the pivotal residue depletion study for the original IVOMEC® Premix for Swine approval. Therefore, **bacitracin methylene disalicylate** fed in combination with ivermectin to swine in the feed does not interfere with the depletion of ivermectin residues.

The level of **bacitracin** recovered from medicated animals for the O-day withdrawal period was less than 0.0125 units/g, which is below the limit of assay detection. Muscle samples from the nonmedicated control animals and the medicated animals sacrificed at 1-day withdrawal did not contain detectable **bacitracin** residues. In accord with the study protocol, muscle samples corresponding to withdrawal days 2, 3, and 5 were not assayed, since no detectable **bacitracin** residue was found in the 1-day samples. Therefore, **ivermectin** fed in combination with **bacitracin methylene disalicylate** to swine does not interfere with the depletion of **bacitracin methylene disalicylate** residues.

VII. AGENCY CONCLUSIONS

The data submitted in support of this original NADA comply with the requirements of Section 512 of the Federal Food, Drug and Cosmetic Act, as amended by the Animal Drug Availability Act (ADAA) of 1996, and implementing regulations, and demonstrate that the combination of ivermectin and bacitracin methylene disalicylate in swine feed under the proposed conditions of use, is safe and effective for the indications stated on labeling.

Results of a pivotal food safety study confirm that neither drug, when administered in combination, interferes with the depletion of residues of the other from edible tissues, and that neither drug interferes with the analytical assay of the other. A preslaughter withdrawal period of 5 days is established for all combination Type B and Type C medicated feeds.

Since adequate directions for use were written for lay persons, the approvals of ivermectin and bacitracin methylene disalicylate Type A medicated articles are for over-the-counter products. The Center for Veterinary Medicine (CVM) has concluded that this combination use shall have over-the-counter marketing status.

The Agency has carefully considered the potential environmental effects of this action and has concluded that the action qualifies for a categorical exclusion from the requirement to prepare an environmental assessment in accordance with 21 CFR 25.33(a)(3).

VIII. APPROVED LABELING (attached)

Specimen (Blue Bird) labeling - Type B medicated feed:

Ivermectin at 14.5 to 364 g/ton and BMD at 1.0 to 2.5 g/lb

Ivermectin at 364 to 910 g/ton and BMD at 1.0 to 2.5 g/lb

Ivermectin at 121 to 728 g/ton and BMD at 1.0 to 6.0 g/lb

Specimen (Blue Bird) labeling - Type C medicated feed: “;

Ivermectin at 1.8 g/ton and BMD at 250 g/ton

Ivermectin at 1.8 g/ton and BMD at 10 g/ton

Ivermectin at 1.8 g/ton and BMD at 30 g/ton

BLUEBIRD
SWINE TYPE B MEDICATED FEED

For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyoststrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via colostrum or milk, when fed during gestation), lice (*Haematopinus suis*) and mange mites (*Sarcoptes scabiei* var. *suis*).

For control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery but where signs of disease have not yet occurred; or following an approved treatment of the disease condition.

ACTIVE DRUG INGREDIENTS

Ivermectin..... 14.5-364 g/ton
Bacitracin methylene disalicylate 1.0-25 g/lb

GUARANTEED ANALYSIS

Crude Protein, not less than	%
Crude Fat, not less than	—0%
Crude Fiber, not more than	—0%

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as listed in 21 CFR 501.110 may be used where applicable.

MIXING DIRECTIONS

This Type B medicated feed must be mixed with feed ingredients (or unmedicated feed) at the rate of 250 to 10 pounds per ton to manufacture a Type C medicated feed containing 1.8 grams of ivermectin and 250 grams of bacitracin methylene disalicylate per ton.

IMPORTANT

Must be thoroughly mixed in feeds before use.
Store at room temperature.

DIRECTIONS FOR USE

Weaned, Growing & Finishing Pigs. Feed the Type C medicated feed, containing **bacitracin methylene disalicylate** at the recommended level of 250 g/ton and ivermectin at the recommended level of 1.8 g/ton (approximately 100 mcg ivermectin per kg body weight per day) as the only feed for 7 consecutive days. A Type C medicated feed containing **bacitracin methylene disalicylate** at the recommended level of 250 g/ton should be fed as the only feed for the duration of the **bacitracin methylene disalicylate** treatment. Diagnosis should be confirmed by a veterinarian when results are not satisfactory.

WARNING: **Withdraw 5 days before slaughter.**
 Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains **IVOME[®]** brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

IVOME[®] is a registered trademark of **Merial Limited**;
BMD[®] is a registered trademark of **Alpharma, Inc.**

Manufactured by

BLUEBIRD FEED COMPANY
City, State, Zip Code .

Net Weight on bag or bulk

BLUEBIRD
SWINE TYPE B MEDICATED FEED

For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyoststrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via **colostrum** or milk, when fed during gestation), lice (*Haematopinus suis*) and mange mites (*Sarcoptes scabiei* var. *suis*).

For control of **clostridial** enteritis caused by *C. perfringens* in suckling piglets.

ACTIVE DRUG INGREDIENTS

Ivermectin.....	14.5 -364 g/ton
Bacitracin methylene disalicylate	1.0-25 g/lb

GUARANTEED ANALYSIS

Crude Protein, not less than	0/0
Crude Fat, not less than	—0%
Crude Fiber, not more than	— 0/0

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as listed in 21 CFR 501. 110 may be used where applicable.

MIXING DIRECTIONS

This Type B medicated feed must be mixed with feed ingredient.s(or unmedicated feed) at the rate of 250 to 10 pounds per ton to manufacture a Type C **medicated** feed containing 1.8 grams of ivermectin and 250 grams of bacitracin methylene **disalicylate** per ton.

IMPORTANT

Must be thoroughly mixed in feeds before use.
Store at room temperature.

DIRECTIONS FOR USE

Pregnant Sows: Feed the Type C medicated feed, containing **bacitracin methylene disalicylate** at the recommended level of 250 g/ton and ivermectin at the recommended level of 1.8 g/ton (100 mcg ivermectin per kg body weight per day) as the only feed for 7 consecutive days. A Type C medicated feed containing **bacitracin methylene disalicylate** at the recommended level of 250 g/ton should be fed as the only feed for the duration of the **bacitracin methylene disalicylate** treatment.

Feed **bacitracin methylene disalicylate** to sows from 14 days before through 21 days **after** farrowing on premises with a history of **clostridial** scours. Diagnosis should be confirmed by a veterinarian when results are not satisfactory.


WARNING: **Withdraw 5** days before slaughter.
 Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains IVOMEC® brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

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BMD® is a registered trademark of **Alpharma**, Inc.

Manufactured by

BLUEBIRD FEED COMPANY 
City, State, Zip Code

Net Weight on bag or bulk

BLUEBIRD
SWINE TYPE B MEDICATED FEED

For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyoststrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via **colostrum** or milk, when fed during gestation), lice (*Haematopinus suis*) and mange mites (*Sarcoptes scabiei* var. *suis*).

For increased rate of weight gain and improved feed efficiency in growing and finishing swine.

ACTIVE DRUG INGREDIENTS

Ivermectin.....	364-910 g/ton
Bacitracin methylene disalicylate	1.0-2.5 g/lb

GUARANTEED ANALYSIS

Crude Protein, not less than	%
Crude Fat, not less than	—0%
Crude Fiber, not more than	—0%

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as listed in 21 CFR 501.110 may be used where applicable.

MIXING DIRECTIONS

This Type B medicated feed must be mixed with feed ingredients, (or unmedicated feed) at the rate of 10 to 4 pounds per ton to manufacture a Type C **medicated feed** containing 1.8 grams of ivermectin and 10 grams of **bacitracin methylene disalicylate** per ton.

IMPORTANT

Must be thoroughly mixed in feeds before use.
Store at room temperature.

DIRECTIONS FOR USE

Weaned, Growing & Finishing Pigs. Feed the Type C medicated feed, containing **bacitracin methylene disalicylate** at the recommended level of 10 #ton and ivermectin at the recommended level of 1.8 g/ton (approximately 100 mcg ivermectin per kg body weight per day) as the only feed for 7 consecutive days. A Type C medicated feed containing **bacitracin methylene disalicylate** should be fed as the only feed for the duration of the **bacitracin methylene disalicylate** treatment for increased rate of weight gain and improved feed efficiency in growing and finishing swine from weaning to market weight.

WARNING: **Withdraw 5 days** before slaughter.
 Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains **IVOMEC®** brand **ivermectin** and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration.

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BMD® is a registered trademark of **Alpharma, Inc.**

Manufactured by

BLUEBIRD FEED COMPANY
City, State, Zip Code

Net Weight on bag or bulk

BLUEBIRD
SWINE TYPE B MEDICATED FEED

For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adults and fourth-stage larvae; *Oesophagostomum* spp., adults and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via colostrum or milk, when fed during gestation), lice (*Haematopinus suis*) and mange mites (*Sarcoptes scabiei* var. *suis*).

For increased rate of weight gain and improved feed efficiency in growing and finishing swine.

ACTIVE DRUG INGREDIENTS

Ivermectin.....	121-728 g/ton
Bacitracin methylene disalicylate.....	1.0-6.0g/lb

GUARANTEED ANALYSIS

Crude Protein, not less than	0/0
Crude Fat, not less than	—0/0
Crude Fiber, not more than	—0/0

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as listed in 21 CFR 501.110 may be used where applicable.

MIXING DIRECTIONS

This Type B medicated feed must be mixed with feed ingredients (or unmedicated feed) at the rate of 30 to 5 pounds per ton to manufacture a Type C medicated feed containing 1.8 grams of ivermectin and 30 grams of bacitracin methylene disalicylate per ton.

IMPORTANT

Must be thoroughly mixed in feeds before use.
Store at room temperature.

DIRECTIONS FOR USE

Weaned, Growing & Finishing Pigs. Feed the Type C medicated feed, containing **ivermectin** methylene **disalicylate** at the recommended level of 30 g/ton and **ivermectin** at the recommended level of 1.8 g/ton (approximately 100 mcg ivermectin per kg body weight per day) as the only feed for 7 consecutive days. A Type C medicated feed containing **ivermectin** methylene **disalicylate** should be fed as the only feed for the duration of the **ivermectin** methylene **disalicylate** treatment for increased rate of weight gain and improved feed **efficiency** in growing and finishing swine from weaning to market weight.

WARNING: **Withdraw 5 days before slaughter.**
 Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains IVOME[®] brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved **landfill** or by incineration.

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Manufactured by

BLUEBIRD FEED COMPANY
City, State, Zip Code

Net Weight on bag or bulk

BLUEBIRD
TYPE C MEDICATED FEED
FOR WEANED, GROWING & FINISHING PIGS

For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyoststrongylus rubidus*, adult and fourth-stage larvae; *Oesophagostomum* spp., adult and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via **colostrum** or milk, when fed during gestation), lice (*Haematopinus suis*) and mange mites (*Sarcoptes scabiei* var. *suis*).

For control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery but where signs of disease have not yet occurred; or following an approved treatment of the disease condition.

ACTIVE DRUG INGREDIENTS

Ivermectin..... 1.8 g/ton
Bacitracin methylene disalicylate 250 g/ton

GUARANTEED ANALYSIS

Protein, not less than 0/0
Fat, not less than —0/o
Fiber, not more than —0/o

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as approved by AAFCO may be used where applicable.

FEEDING DIRECTIONS

To provide the recommended level of 250 g bacitracin methylene disalicylate/ton and 1.8 g ivermectin/ton (approximately 100 mcg ivermectin per kg of body weight per day), feed as the only feed for 7 consecutive days. When this feed is consumed resume feeding 250 g bacitracin methylene disalicylate/ton for the duration of the bacitracin methylene disalicylate treatment. Diagnosis should be **confirmed** by a veterinarian when results are not satisfactory.

WARNING: **Withdraw 5 days** before slaughter.
 Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains IVOMEC[®] brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers.

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BMD[®] is a registered trademark of Alpharma, Inc.

Manufactured by

BLUEBIRD FEED COMPANY
City, State, Zip Code

Net Weight on bag or bulk

BLUEBIRD
TYPE C MEDICATED FEED
PREGNANT SOWS

For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adult and fourth-stage larvae; *Oesophagostomum* spp., adult and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via **colostrum** or milk, when fed during gestation), lice (*Haematopinus suis*) and mange mites (*Sarcoptes scabiei* var. *suis*).

For control of **clostridial** enteritis caused by *C. perfringens* in suckling piglets.

ACTIVE DRUG INGREDIENTS

Ivermectin.....	1.8 g/ton
Bacitracin methylene disalicylate	250g/ton

GUARANTEED ANALYSIS

Protein, not less than	0/0
Fat, not less than	—0%
Fiber, not more than	—0%

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as approved by AAFCO may be used where applicable.

FEEDING DIRECTIONS

To provide the recommended level of 250 g bacitracin methylene disalicylate/ton and 1.8 g ivermectin/ton (100 mcg ivermectin per kg of body weight per day), feed as the **only** feed for 7 consecutive days. When this feed is consumed, resume feeding 250 g bacitracin **methylene disalicylate/ton** for the duration of the **bacitracin methylene disalicylate treatment**.

Feed **bacitracin methylene disalicylate** to sows from 14 days before through 21 days after **farrowing** on premises with a history of **clostridial** scours. Diagnosis should be confirmed by a veterinarian when results are not satisfactory.

WARNING: **Withdraw 5 days** before slaughter.
 Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains IVOME[®] brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers.

IVOME[®] is a registered trademark of Merial Limited;
BMD[®] is a registered trademark of Alpharma, Inc.

Manufactured by

BLUEBIRD FEED COMPANY
City, State, Zip Code

Net Weight on bag or bulk

BLUEBIRD
TYPE C MEDICATED FEED
FOR WEANED, GROWING & FINISHING PIGS

For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyoststrongylus rubidus*, adult and fourth-stage larvae; *Oesophagostomum* spp., adult and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via **colostrum** or milk, when fed during gestation), lice (*Haematopinus suis*) and mange mites (*Sarcoptes scabiei* var. *suis*).

For increased rate of weight gain and improved feed efficiency in growing and finishing swine.

ACTIVE DRUG INGREDIENTS

Ivermectin..... 1.8 /ton
Bacitracin methylene disalicylate 10 g/ton

GUARANTEED ANALYSIS

Protein, not less than %
Fat, not less than —0%
Fiber, not more than —0%

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as approved by AAFCO may be used where applicable.

FEEDING DIRECTIONS

To provide the recommended level of 10 g bacitracin methylene disalicylate/ton and 1.8 g ivermectin/ton (approximately 100 mcg ivermectin per kg of body weight per day), feed as the only feed for 7 consecutive days. When this feed is consumed, resume feeding bacitracin methylene disalicylate.

WARNING: **Withdraw 5 days** before slaughter.
 Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

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Manufactured by

BLUEBIRD FEED COMPANY
City, State, Zip Code

Net Weight on bag or bulk

BLUEBIRD
TYPE C MEDICATED FEED
FOR WEANED, GROWING & FINISHING PIGS

For the treatment and control of gastrointestinal roundworms (*Ascaris suum*, adults and fourth-stage larvae; *Ascarops strongylina*, adults; *Hyostrongylus rubidus*, adult and fourth-stage larvae; *Oesophagostomum* spp., adult and fourth-stage larvae), kidneyworms (*Stephanurus dentatus*, adults and fourth-stage larvae), lungworms (*Metastrongylus* spp., adults), threadworms (*Strongyloides ransomi*, adults and somatic larvae, and prevention of transmission of infective larvae to piglets, via colostrum or milk, when fed during gestation), lice (*Haematopinus suis*) and mange mites (*Sarcoptes scabiei* var. *suis*).

For increased rate of weight gain and improved feed efficiency in growing finishing swine.

ACTIVE DRUG INGREDIENTS

Ivermectin 1.8 /ton
Bacitracin methylene disalicylate 30 g/ton

GUARANTEED ANALYSIS

protein, not less than _' %
Fat, not less than %
Fiber, not more than — 0 %

INGREDIENTS

Each ingredient must be specifically named (unless stated as such in the guaranteed analysis listing) in accordance with the names and definitions adopted by AAFCO. Collective terms as approved by AAFCO maybe used where applicable.

FEEDING DIRECTIONS

To provide the recommended level of 30 g bacitracin methylene disalicylate/ton and 1.8 g ivermectin/ton (approximately 100 mcg ivermectin per kg of body weight per day), feed as the only feed for 7 consecutive days. When this feed is consumed, resume feeding bacitracin methylene disalicylate.

WARNING: **Withdraw 5 days before slaughter.**
 Keep this and all drugs out of the reach of children.

CAUTION: Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

This product contains IVOMECS[®] brand ivermectin and has been formulated specifically for use in swine only. This product should not be used for other animal species. Do not permit water runoff from swine production sites to directly enter lakes, streams, or ponds. Do not contaminate water by direct application or by the improper disposal of drug containers.

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